Simponi Aria® (Golimumab) Injection for Intravenous Infusion

Policy Number: CS2024D0051V
Effective Date: May 1, 2024

Instructions for Use

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Commercial Policy

- Simponi Aria® (Golimumab) Injection for Intravenous Infusion

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Arizona	Refer to the state's Medicaid clinical policy
Indiana	Refer to the state's Medicaid clinical policy
Kansas	Refer to the state's Medicaid clinical policy
Louisiana	Refer to the state's Medicaid clinical policy
North Carolina	None
Ohio	Simponi Aria® (Golimumab) Injection for Intravenous Infusion (for Ohio Only)
Pennsylvania	Refer to the state's Medicaid clinical policy
Washington	Refer to the state's Medicaid clinical policy

Coverage Rationale

This policy refers only to Simponi Aria (golimumab) injection for intravenous infusion for the treatment of ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis. Simponi for self-administered subcutaneous injection is obtained under the pharmacy benefit, and is indicated in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

Simponi Aria is proven and medically necessary for the treatment of:

- **Ankylosing spondylitis** when **all** of the following criteria are met:[1]
  - For **initial therapy**, **all** of the following:
    - Diagnosis of active ankylosing spondylitis (AS); **and**
    - **One** of the following:

- History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced; **or**
- Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of ankylosing spondylitis [e.g., Cimzia (certolizumab), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]; **or**
- Patient is currently on Simponi Aria

and

- Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis; **and**
- Patient is not receiving Simponi Aria in combination with either of the following:
  - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)][5]

  and
- Prescribed by or in consultation with a rheumatologist; **and**
- Initial authorization is for no more than 12 months

o For **continuation of therapy**, **all** of the following:

- Patient has previously received Simponi Aria injection for intravenous infusion; **and**
- Documentation of positive clinical response to Simponi Aria; **and**
- Simponi Aria dosing for ankylosing spondylitis is in accordance with the FDA labeled dosing; **and**
- Patient is not receiving Simponi Aria in combination with either of the following:
  - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)][5]

  and
- Reauthorization is for no more than 12 months

- **Psoriatic arthritis** when **all** of the following criteria are met:[1]

o For **initial therapy**, **all** of the following:

- Diagnosis of active psoriatic arthritis (PsA); **and**
- **One** of the following:
  - History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced; **or**
  - Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]; **or**
  - Patient is currently on Simponi Aria

  and
- Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis; **and**
- Patient is not receiving Simponi Aria in combination with any of the following:
  - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)];[5] **or**
  - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

  and
- Prescribed by or in consultation with **one** of the following:
  - Rheumatologist; **or**
  - Dermatologist

  and
- Authorization is for no more than 12 months

o For **continuation of therapy**, **all** of the following:

- Patient has previously received Simponi Aria injection for intravenous infusion; **and**
- Documentation of positive clinical response to Simponi Aria; **and**
- Simponi Aria dosing for psoriatic arthritis is in accordance with the FDA labeled dosing; **and**

        - Patient is not receiving Simponi Aria in combination with any of the following:
            - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)];[5] **or**
            - Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

          and
        - Reauthorization is for no more than 12 months
- **Rheumatoid arthritis** when **all** of the following criteria are met:[1,8]
    - For **initial therapy**, **all** of the following:
        - Diagnosis of moderately to severely active rheumatoid arthritis (RA); **and**
        - **One** of the following:
            - History of failure intolerance to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; **or**
            - Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Cimzia (certolizumab), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]; **or**
            - Patient is currently on Simponi Aria

          and
        - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for rheumatoid arthritis; **and**
        - Patient is not receiving Simponi Aria in combination with either of the following:
            - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)][5,6]

          and
        - Prescribed by or in consultation with a rheumatologist; **and**
        - Initial authorization is for no more than 12 months
    - For **continuation of therapy**, **all** of the following:
        - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
        - Documentation of positive clinical response to Simponi Aria; **and**
        - Simponi Aria dosing for rheumatoid arthritis is in accordance with the FDA labeled dosing; **and**
        - Patient is not receiving Simponi Aria in combination with either of the following:
            - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)][5,6]

          and
        - Reauthorization is for no more than 12 months
- **Polyarticular juvenile idiopathic arthritis** when **all** of the following criteria are met:
    - For **initial therapy, all** of the following:
        - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA); **and**
        - Simponi Aria is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; **and**
        - Patient is not receiving Simponi Aria in combination with either of the following:
            - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
            - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

          and
        - Prescribed by or in consultation with a rheumatologist; **and**
        - Initial authorization is for no more than 12 months
    - For **continuation of therapy**, **all** of the following:
        - Patient has previously received Simponi Aria injection for intravenous infusion; **and**
        - Documentation of positive clinical response; **and**
        - Simponi Aria is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; **and**

- Patient is not receiving Simponi Aria in combination with either of the following:
  - Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]; **or**
  - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

  and
- Reauthorization is for no more than 12 months

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J1602	Injection, golimumab, 1 mg, for intravenous use

Diagnosis Code	Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot

Diagnosis Code	Description
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee

Diagnosis Code	Description
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand

Diagnosis Code	Description
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement

Diagnosis Code	Description
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.8A	Other rheumatoid arthritis with rheumatoid factor of other specified site
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified

Diagnosis Code	Description
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.1	Adult-onset Still's disease
M06.20	Rheumatoid bursitis, unspecified site
M06.211	Rheumatoid bursitis, right shoulder
M06.212	Rheumatoid bursitis, left shoulder
M06.219	Rheumatoid bursitis, unspecified shoulder
M06.221	Rheumatoid bursitis, right elbow
M06.222	Rheumatoid bursitis, left elbow
M06.229	Rheumatoid bursitis, unspecified elbow
M06.231	Rheumatoid bursitis, right wrist
M06.232	Rheumatoid bursitis, left wrist
M06.239	Rheumatoid bursitis, unspecified wrist
M06.241	Rheumatoid bursitis, right hand
M06.242	Rheumatoid bursitis, left hand
M06.249	Rheumatoid bursitis, unspecified hand
M06.251	Rheumatoid bursitis, right hip
M06.252	Rheumatoid bursitis, left hip
M06.259	Rheumatoid bursitis, unspecified hip

Diagnosis Code	Description
M06.261	Rheumatoid bursitis, right knee
M06.262	Rheumatoid bursitis, left knee
M06.269	Rheumatoid bursitis, unspecified knee
M06.271	Rheumatoid bursitis, right ankle and foot
M06.272	Rheumatoid bursitis, left ankle and foot
M06.279	Rheumatoid bursitis, unspecified ankle and foot
M06.28	Rheumatoid bursitis, vertebrae
M06.29	Rheumatoid bursitis, multiple sites
M06.30	Rheumatoid nodule, unspecified site
M06.311	Rheumatoid nodule, right shoulder
M06.312	Rheumatoid nodule, left shoulder
M06.319	Rheumatoid nodule, unspecified shoulder
M06.321	Rheumatoid nodule, right elbow
M06.322	Rheumatoid nodule, left elbow
M06.329	Rheumatoid nodule, unspecified elbow
M06.331	Rheumatoid nodule, right wrist
M06.332	Rheumatoid nodule, left wrist
M06.339	Rheumatoid nodule, unspecified wrist
M06.341	Rheumatoid nodule, right hand
M06.342	Rheumatoid nodule, left hand
M06.349	Rheumatoid nodule, unspecified hand
M06.351	Rheumatoid nodule, right hip
M06.352	Rheumatoid nodule, left hip
M06.359	Rheumatoid nodule, unspecified hip
M06.361	Rheumatoid nodule, right knee
M06.362	Rheumatoid nodule, left knee
M06.369	Rheumatoid nodule, unspecified knee
M06.371	Rheumatoid nodule, right ankle and foot
M06.372	Rheumatoid nodule, left ankle and foot
M06.379	Rheumatoid nodule, unspecified ankle and foot
M06.38	Rheumatoid nodule, vertebrae
M06.39	Rheumatoid nodule, multiple sites
M06.8A	Other specified rheumatoid arthritis, other specified site
M06.80	Other specified rheumatoid arthritis, unspecified site
M06.811	Other specified rheumatoid arthritis, right shoulder
M06.812	Other specified rheumatoid arthritis, left shoulder
M06.819	Other specified rheumatoid arthritis, unspecified shoulder
M06.821	Other specified rheumatoid arthritis, right elbow
M06.822	Other specified rheumatoid arthritis, left elbow
M06.829	Other specified rheumatoid arthritis, unspecified elbow
M06.831	Other specified rheumatoid arthritis, right wrist
M06.832	Other specified rheumatoid arthritis, left wrist

Diagnosis Code	Description
M06.839	Other specified rheumatoid arthritis, unspecified wrist
M06.841	Other specified rheumatoid arthritis, right hand
M06.842	Other specified rheumatoid arthritis, left hand
M06.849	Other specified rheumatoid arthritis, unspecified hand
M06.851	Other specified rheumatoid arthritis, right hip
M06.852	Other specified rheumatoid arthritis, left hip
M06.859	Other specified rheumatoid arthritis, unspecified hip
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.871	Other specified rheumatoid arthritis, right ankle and foot
M06.872	Other specified rheumatoid arthritis, left ankle and foot
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot
M06.88	Other specified rheumatoid arthritis, vertebrae
M06.89	Other specified rheumatoid arthritis, multiple sites
M06.9	Rheumatoid arthritis, unspecified
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site
M08.1	Juvenile ankylosing spondylitis

Diagnosis Code	Description
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip

Diagnosis Code	Description
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, vertebrae
M08.89	Other juvenile arthritis, multiple sites
M08.90	Juvenile arthritis, unspecified, unspecified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region

Diagnosis Code	Description
M45.9	Ankylosing spondylitis of unspecified sites in spine

Background

Golimumab is a human anti-tumor necrosis factor (TNF) monoclonal antibody that targets both soluble and transmembrane bioactive forms of TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage, and tissue.[1]

Clinical Evidence

Proven

Ankylosing Spondylitis

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 208 adult patients with active ankylosing spondylitis (AS) and inadequate response or intolerance to NSAIDs.[1] Patients had a diagnosis of definite AS for at least 3 months according to modified New York criteria. Patients had symptoms of active disease [Bath AS Disease Activity Index (BASDAI) ≥ 4, VAS for total back pain of ≥ 4, on scales of 0 to 10 cm (0 to 100 mm), and a hsCRP level of ≥ 0.3 mg/dL (3 mg/L)]. Patients were randomized to receive either golimumab 2 mg/kg (n = 105) or placebo (n = 103) as a 30-minute intravenous infusion at weeks 0, 4 and 12. All patients on placebo received golimumab at week 16, week 20, and every 8 weeks thereafter through week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at week 20 and every 8 weeks through week 52. Patients were allowed to continue stable doses of concomitant methotrexate (MTX), sulfasalazine (SSZ), hydroxychloroquine (HCQ), low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day), and/or NSAIDs during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an Assessment in Ankylosing Spondylitis (ASAS) 20 response at week 16. In this trial, golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ASAS 20 response at week 16, where a greater percentage of patients treated with golimumab achieved a low level of disease activity [< 2 (on a scale of 0 to 10 cm) in all four ASAS domains] compared with patients treated with placebo (16.2% vs. 3.9%). General health status was assessed by the 36-item Short Form Health Survey (SF-36). Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary and mental component summary scores and in all eight domains of the SF-36. Golimumab-treated patients showed significant improvement compared with placebo-treated patients in health-related quality of life as assessed by the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL).

Psoriatic Arthritis

The efficacy and safety of golimumab were evaluated in a multicenter, randomized, double-blind, placebo-controlled trial in 480 adult patients with active psoriatic arthritis (PsA) despite NSAID or DMARD therapy. Previous treatment with a biologic was not allowed. Patients in this trial had a diagnosis of PsA for at least six months and had symptoms of active disease (≥ 5 swollen joints and ≥ 5 tender joints and a CRP level of ≥ 0.6 mg/dL). Patients were randomized to either receive golimumab 2 mg/kg (n = 241) or placebo (n = 239) as a 30-minute intravenous infusion at weeks 0, 4, 12 and 20. All patients on placebo received golimumab at week 24, week 28, and every 8 weeks thereafter through week 52. Patients in the golimumab treatment group continued to receive golimumab infusions at week 28 and every 8 weeks through week 52. Patients were allowed to continue stable doses of MTX, NSAIDs, and low dose oral corticosteroids (equivalent to ≤ 10 mg of prednisone per day) during the trial. The use of other DMARDs including cytotoxic agents or other biologics was prohibited. The primary endpoint was the percentage of patients achieving an ACR 20 response at week 14. Patients with each subtype of PsA were enrolled, including polyarticular arthritis with absence of rheumatoid nodules (44%), asymmetric peripheral arthritis (19%), distal interphalangeal joint involvement (8.1%), spondylitis with peripheral arthritis (25%), and arthritis mutilans (4.8%). During the trial, concomitant medications used included MTX (70%), oral corticosteroids (28%), and NSAIDs (71%). Golimumab, compared with placebo, resulted in a significant improvement in signs and symptoms as demonstrated by the percentage of patients with an ACR 20 response at week 14. Similar ACR 20 responses at week 24 were observed in patients with different PsA subtypes. ACR 20 responses observed in the golimumab-treated groups were similar in patients who were or were not receiving concomitant MTX. Patients with enthesitis at baseline were evaluated for mean improvement using the Leeds Enthesitis Index (LEI) on a scale of 0-6. Golimumab-treated patients showed a significantly greater improvement in enthesitis, with a mean reduction of 1.8 as compared with a mean reduction in placebo-treated patients of 0.8 at week 14. Patients with dactylitis at baseline were

evaluated for mean improvement on a scale of 0-60. Golimumab-treated patients showed a significantly greater improvement, with a mean reduction of 7.8 compared with a mean reduction of 2.8 in placebo-treated patients at week 14. Golimumab inhibited the progression of structural damage compared with placebo, as assessed by total modified vdH-S score. At week 24, a greater proportion of patients in the golimumab group (72%) had no progression of structural damage (change in the total modified vdH-S score ≤ 0), compared to 43% of patients in the placebo group. Improvement in physical function as assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved clinically meaningful improvement of ≥ 0.3 in HAQ-DI score from baseline was greater in the golimumab-treated group compared to placebo at week 14 (69% compared to 32%). General health status was assessed by the 36-item Short Form Health Survey (SF-36). Patients receiving golimumab demonstrated greater improvement from baseline compared with placebo in physical component summary, mental component summary scores and in all eight domains of the SF-36.

Rheumatoid Arthritis

In the extension phase to the GO-FURTHER pivotal study, the long term extension study of golimumab plus methotrexate (MTX) for rheumatoid arthritis evaluated the efficacy, pharmacokinetics, immunogenicity and radiographic progression, through 100 weeks of therapy, where safety was monitored through 112 weeks.[6] In the original trial, 592 patients with active RA were randomized (2:1) to receive intravenous (IV) golimumab 2 mg/kg plus MTX or placebo plus MTX at weeks 0, 4, and every 8 weeks thereafter.[2] Patients receiving placebo were able to cross over at either week 16 or week 24 to active therapy. In total, 486 patients (82.1%) continued golimumab therapy for 100 weeks. Efficacy assessments included the American College of Rheumatology 20%, 50%, 70% (ACR20, ACR50, ACR70) response criteria, 28 joint count disease activity score using the C-reactive protein level, physical function, and quality of life (QoL) measures, and changes in the modified Sharp/van der Heijde scores (SHS). Following treatment at week 100, in both groups combined, 68.1% of patients had an ACR20 response, 43.8% had an ACR50, and 23.5% had an ACR70 response. More than 80% of all patients had a good or moderate DAS28-CRP response at week 100, and approximately 28% achieved DAS28-CRP < 2.6. For patient reported outcomes, improvements in SF-36 PCS, MCS, FACIT-Fatigue, EQ-5D VAS scores were sustained through week 112 in both treatment groups. At week 100, the mean change from baseline in total SHS score was significantly lower in Group 1 than in Group 2 (0.74 vs. 2.10; p = 0.005) and 61.8% (n = 244 of 395) of patients in Group 1 and 54.8% (n = 108 of 197) of patients in Group 2 had a change from baseline in total SHS of ≤ 0. When evaluated by progression beyond the smallest detectable change (3.22) in total SHS, 16.7% (n = 66 of 395) of patients in Group 1 and 23.9% (n = 47 of 197) in Group 2 demonstrated radiographic progression from baseline to week 100. The mean change in total SHS score from week 52 to week 100 when all patients were receiving golimumab was numerically lower in Group 1 (0.56) than in Group 2 (0.80); the median change was 0 in both groups. After 112 weeks, a total of 481 patients completed the safety follow-up with 79.1% had at least one adverse event, and 18.2% having had a serious adverse event. After 100 weeks of treatment only 6.7% (n = 37 of 553) of patients developed antibodies to golimumab, with 86.5% positive for neutralizing antibodies. The authors concluded that treatment with IV golimumab plus MTX afforded a clinical response that was maintained through week 100. Radiographic progression following treatment was clinically insignificant between week 52 and week 100.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

The efficacy of golimumab in pediatric patients with pJIA is based on the pharmacokinetic exposure and extrapolation of the established efficacy of golimumab in RA patients. Efficacy of golimumab was also assessed in a multicenter, open-label, single-arm study in 127 children (2 to < 18 years of age) with JIA with active polyarthritis despite treatment with MTX for at least 2 months (Trial pJIA, NCT02277444). The polyarticular JIA patient subtypes at study entry included: rheumatoid factor negative (43%), rheumatoid factor positive (35%), enthesitis-related arthritis (9%), oligoarticular extended (6%), juvenile psoriatic arthritis (4%), and systemic JIA without systemic manifestations (3%). All patients received golimumab 80 mg/m^2 as an intravenous infusion at week 0, 4, and every 8 weeks through week 52. Patients continued stable doses of MTX weekly through week 28; after week 28, changes in MTX dose were permitted. Efficacy was assessed as supportive endpoints through week 52. The efficacy was generally consistent with responses in patients with RA.

Professional Societies

Rheumatoid Arthritis

The 2021 American College of Rheumatology (ACR) RA updated treatment guideline addresses the use of DMARDS, including conventional synthetic DMARDs, biologic DMARDs, and targeted synthetic DMARDS and glucocorticoids, and the use of DMARDs in certain high-risk populations (i.e., those with liver disease, heart failure, lymphoproliferative disorders, previous serious infections, and nontuberculosis myobacterial lung disease).[18] The guideline recommendations apply to common clinical

situations, since the panel considered issues common to most patients, not exceptions. Recommendations are classified as either strong or conditional. A strong recommendation means that the panel was confident that the desirable effects of following the recommendation outweigh the undesirable effects (or vice versa), so the course of action would apply to most patients, and only a small proportion would not want to follow the recommendation. A conditional recommendation means that the desirable effects of following the recommendation probably outweigh the undesirable effects, so the course of action would apply to the majority of patients, but some may not want to follow the recommendation. As a result, conditional recommendations are preference sensitive and warrant a shared decision-making approach.

Recommendations for DMARD-Naïve Patients

- A treat-to-target approach is strongly recommended over usual care for patients who have not been previously treated with bDMARDs or tsDMARDs regardless of disease activity level.
- A minimal initial treatment goal of low disease activity is conditionally recommended over a goal of remission.
- Moderate-to-high disease activity:
  - Methotrexate is strongly recommended over hydroxychloroquine or sulfasalazine.
  - Methotrexate is conditionally recommended over leflunomide.
  - Methotrexate monotherapy is strongly recommended over bDMARD or tsDMARD monotherapy.
  - Methotrexate monotherapy is conditionally recommended over dual or triple csDMARD therapy.
  - Methotrexate monotherapy is conditionally recommended over methotrexate plus a tumor necrosis factor (TNF) inhibitor.
  - Initiation of a csDMARD without short-erm (< 3 months) glucocorticoids is conditional recommended over initiation of a csDMARD with short-term glucocorticoids.
  - Initiation of a csDMARD without longer-term (≥ 3 months) glucocorticoids is strongly recommended over initiation of a csDMARD with longer-term glucocorticoids.
- Low disease activity:
  - Hydroxychloroquine is conditionally recommended over other csDMARDs, sulfasalazine is conditionally recommended over methotrexate, and methotrexate is conditionally recommended over leflunomide.

Recommendations for DMARD-Experienced Patients

- A treat-to-target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs.
- Methotrexate monotherapy is conditionally recommended over the combination of methotrexate plus a bDMARD or tsDMARD.
- Oral methotrexate is conditionally recommended over subcutaneous methotrexate for patients initiating methotrexate.
- Initiation/titration of methotrexate to a weekly dose of at least 15 mg within 4 to 6 weeks is conditionally recommended over initiation/titration to a weekly dose of less than 15 mg.
- A split dose of oral methotrexate over 24 hours or weekly subcutaneous injections, and/or an increased dose of folic/folinic acid, is conditionally recommended over switching to alternative DMARD(s) for patients not tolerating oral weekly methotrexate.
- Switching to subcutaneous methotrexate is conditionally recommended over the addition of/ switching to alternative DMARD(s) for patients taking oral methotrexate who are not at target.

Recommendations for Treatment Modification

- Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy (i.e., addition of sulfasalazine and hydroxychloroquine) for patients taking maximally tolerated doses of methotrexate who are not at target.
- Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target.
- Addition of/switching to DMARDs is conditionally recommended over continuation of glucocorticoids for patients taking glucocorticoids to remain at target.
- Addition of/switching to DMARDs [with or without intraarticular (IA) glucocorticoids] is conditionally recommended over the use of IA glucocorticoids alone for patients taking DMARDs who are not at target.
- Continuation of all DMARDs at their current dose is conditionally recommended over a dose reduction of a DMARD, dose reduction is conditionally recommended over gradual discontinuation of a DMARD, and gradual discontinuation is conditionally recommended over abrupt discontinuation of a DMARD for patients who are at target for at least 6 months.

- Gradual discontinuation of sulfasalazine is conditionally recommended over gradual discontinuation of hydroxychloroquine for patients taking triple therapy who wish to discontinue a DMARD.
- Gradual discontinuation of methotrexate is conditionally recommended over gradual discontinuation of the bDMARD or tsDMARD for patients taking methotrexate plus a bDMARD or tsDMARD who wish to discontinue a DMARD.

Recommendations for Specific Patient Populations

- Subcutaneous nodules:
  - Methotrexate is conditionally recommended over alternative DMARDs for patients with subcutaneous nodules who have moderate-to high disease activity. Switching to a non-methotrexate DMARD is conditionally recommended over continuation of methotrexate for patients taking methotrexate with progressive subcutaneous nodules.
- Pulmonary disease:
  - Methotrexate is conditionally recommended over alternative DMARDs for the treatment of inflammatory arthritis for patients with clinically diagnosed mild and stable airway or parenchymal lung disease, or incidental disease detected on imaging, who have moderate-to-high disease activity.
- Lymphoproliferative disorder:
  - Rituximab is conditionally recommended over other DMARDs for patients who have a previous lymphoproliferative disorder for which rituximab is an approved treatment and who have moderate-to-high disease activity.
- Heart failure:
  - Addition of a non-TNF inhibitor bDMARD or tsDMARD is conditionally recommended over addition of a TNF inhibitor for patients with New York Heart Association (NYHA) class III or IV heart failure and an inadequate response to csDMARDs.
  - Switching to a non-TNF inhibitor bDMARD or tsDMARD is conditionally recommended over continuation of a TNF inhibitor for patients taking a TNF inhibitor who develop heart failure.
- Hepatitis B:
  - Prophylactic antiviral therapy is strongly recommended over frequent monitoring of viral load and liver enzymes alone for patients initiating rituximab who are hepatitis B core antibody positive (regardless of hepatitis B surface antigen status).
  - Prophylactic antiviral therapy is strongly recommended over frequent monitoring alone for patients initiating any bDMARD or tsDMARD who are hepatitis B core antibody positive and hepatitis B surface antigen positive.
  - Frequent monitoring alone of viral load and liver enzymes is conditionally recommended over prophylactic antiviral therapy for patients initiating a bDMARD other than rituximab or a tsDMARD who are hepatitis B core antibody positive and hepatitis B surface antigen negative.
- Nonalcoholic fatty liver disease (NAFLD):
  - Methotrexate is conditionally recommended over alternative DMARDs for DMARD-naive patients with NAFLD, normal liver enzymes and liver function tests, and no evidence of advanced liver fibrosis who have moderate-to-high disease activity.
  - Persistent hypogammaglobulinemia without infection.
  - In the setting of persistent hypogammaglobulinemia without infection, continuation of rituximab therapy for patients at target is conditionally recommended over switching to a different bDMARD or tsDMARD.
- Serious Infections:
  - Addition of csDMARDs is conditionally recommended over addition of a bDMARD or tsDMARD for patients with a serious infection within the previous 12 months who have moderate-to-high disease activity despite csDMARD monotherapy.
  - Addition of/switching to DMARDs is conditionally recommended over initiation/dose escalation of glucocorticoids for patients with a serious infection within the previous 12 months who have moderate-to-high disease activity.
- Lung Disease:
  - Use of the lowest possible dose of glucocorticoids (discontinuation if possible) is conditionally recommended over continuation of glucocorticoids without dose modification for patients with NTM lung disease. This recommendation is based on studies suggesting an increased risk of NTM lung disease in patients receiving either inhaled or oral glucocorticoids. (54,55)
  - Addition of csDMARDs is conditionally recommended over addition of a bDMARD or tsDMARD for patients with NTM lung disease who have moderate-to-high disease activity despite csDMARD monotherapy. This recommendation is based on the lower expected risk of NTM lung disease associated with csDMARDs compared to bDMARDs and tsDMARDs. (56)

- Abatacept is conditionally recommended over other bDMARDs and tsDMARDs for patients with NTM lung disease who have moderate-to high disease activity despite csDMARDs.

Psoriatic Arthritis

In 2018, the American College of Rheumatology and the National Psoriasis Foundation published a treatment guideline for the treatment of psoriatic arthritis. In regard to psoriatic arthritis (PsA) and TNFis, the guidelines state:

- Recommendations for the initial treatment of patients with active psoriatic arthritis who are oral small molecule (OSM) and other treatment-naive:
  - Treat with a TNFi biologic over an OSM:
    - Conditional recommendation based on low-quality evidence; may consider an OSM if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic as the first therapy, or has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.
  - Treat with a TNFi biologic over an IL-17i biologic:
    - Conditional recommendation based on very-low-quality evidence; may consider an IL-17i biologic if the patient has severe psoriasis or has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.
  - Treat with a TNFi biologic over an IL-12/23i biologic:
    - Conditional recommendation based on very-low-quality evidence; may consider an IL-12/23i biologic if the patient has severe psoriasis, prefers less frequent drug administration, or has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.
- Recommendations for treatment of patients with active psoriatic arthritis despite treatment with an OSM:
  - Switch to a TNFi biologic over a different OSM:
    - Conditional recommendation based on moderate-quality evidence; may consider switching to a different OSM if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease, if the patient prefers an oral versus parenteral therapy, or in patients without evidence of severe PsA or severe psoriasis.
  - Switch to a TNFi biologic over an IL-17i biologic:
    - Conditional recommendation based on moderate-quality evidence; may consider an IL-17i if the patient has severe psoriasis and/or has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease, and/or a family history of demyelinating disease such as multiple sclerosis.
  - Switch to a TNFi biologic over an IL-12/23i biologic:
    - Conditional recommendation based on moderate-quality evidence; may consider an IL-12/23i if the patient has severe psoriasis and/or contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease, or prefers less frequent drug administration.
  - Switch to a TNFi biologic over abatacept:
    - Conditional recommendation based on low-quality evidence; may consider abatacept if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.
  - Switch to a TNFi biologic over tofacitinib:
    - Conditional recommendation based on low-quality evidence; may consider tofacitinib if the patient has contraindications to TNFi biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease, or prefers oral medication.
  - Switch to a TNFi biologic monotherapy over MTX and a TNFi biologic combination therapy:
    - Conditional recommendation based on low-quality evidence; may consider MTX and TNFi biologic combination therapy if the patient has severe skin manifestations, has had a partial response to current MTX therapy, has concomitant uveitis (since uveitis may respond to MTX therapy), and if the current TNFi biologic is infliximab or adalimumab.
- Recommendations for treatment of patients with active psoriatic arthritis despite treatment with a TNFi biologic, as monotherapy or in combination with MTX:
  - Switch to a different TNFi biologic over switching to an IL-17i biologic:
    - Conditional recommendation based on low-quality evidence; may consider an IL-17i if the patient had a primary TNFi biologic efficacy failure or a TNFi biologic-associated serious adverse event or severe psoriasis.
  - Switch to a different TNFi biologic over switching to an IL-12/23i biologic:

        - Conditional recommendation based on low-quality evidence; may consider an IL-12/23i if the patient had a primary TNFi biologic efficacy failure or a TNFi biologic–associated serious adverse effect or prefers less frequent drug administration.
    - Switch to a different TNFi biologic over switching to abatacept:
        - Conditional recommendation based on low-quality evidence; may consider abatacept if the patient had a primary TNFi biologic efficacy failure or TNFi biologic–associated serious adverse effect.
    - Switch to a different TNFi biologic over switching to tofacitinib:
        - Conditional recommendation based on low-quality evidence; may consider tofacitinib if the patient prefers an oral therapy or had a primary TNFi biologic efficacy failure or a TNFi biologic-associated serious adverse effect.
    - Switch to a different TNFi biologic (with or without MTX) over adding MTX to the same TNFi biologic monotherapy:
        - Conditional recommendation based on very-low-quality evidence; may consider adding MTX when patients have demonstrated partial response to the current TNFi biologic therapy, especially if the TNFi biologic is a monoclonal antibody.
    - Switch to a different TNFi biologic monotherapy over switching to a different TNFi biologic and MTX combination therapy:
        - Conditional recommendation based on very-low-quality evidence; may consider switching to a TNFi biologic and MTX combination therapy if the current TNFi biologic is infliximab.
- In adult patients with active PsA despite treatment with a TNFi biologic and MTX combination therapy:
    - Switch to a different TNFi biologic+MTX over switching to a different TNFi biologic monotherapy:
        - Conditional recommendation based on very-low-quality evidence; may consider switching to a different TNFi biologic monotherapy if the patient has demonstrated MTX-associated adverse events, prefers to receive fewer medications, or perceives MTX as a burden.

Ankylosing Spondylitis

In 2019, the American College of Rheumatology, Spondylitis Association of America and Spondyloarthritis Research and Treatment Network published updated recommendations for the treatment of patients with ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (SpA) which addressed the use of Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), tumor necrosis factor inhibitor (TNFi) biosimilars, and biologic tapering/discontinuation.[19] Recommendations for AS and nonradiographic axial SpA are similar.

- TNFi are recommended over Cosentyx (secukinumab) or Taltz (ixekizumab) as the first biologic to be used.
- Cosentyx (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi.
- TNFi, Cosentyx (secukinumab), and Taltz (ixekizumab) are favored over Xeljanz (tofacitinib).
- Co-administration of low-dose methotrexate with TNFi is not recommended, nor is a strict treat-to-target strategy or discontinuation or tapering of biologics in patients with stable disease.
- Sulfasalazine is recommended only for persistent peripheral arthritis when TNFi are contraindicated.
- For patients with unclear disease activity, spine or pelvis magnetic resonance imaging could aid assessment.
- Routine monitoring of radiographic changes with serial spine radiographs is not recommended.

In 2017, the British Society for Rheumatology (BSR) and the British Health Professionals in Rheumatology published a revision to their 2005 BSR guidelines to provide guidance for clinicians in the United Kingdom prescribing biologic drugs for the treatment of axial spondyloarthritis (axSpA), including ankylosing spondylitis. This includes the criteria for starting treatment, choice of drug, and assessing response. In regard to tumor necrosis factor inhibitors (TNFi), the guidelines recommend:

- The effectiveness of biologics in axSpA:
    - Anti-TNF therapy is effective at reducing disease activity and spinal pain in axSpA. While short-term MRI data support the efficacy of anti-TNF therapy in treating inflammatory SIJ and spinal lesions in axSpA, evidence for anti-TNF therapy on radiographic disease progression is currently limited.
    - Currently there is insufficient evidence to recommend the use of other biologic agents in axSpA.
- Initiating treatment:
    - Patients should be considered for anti-TNF therapy if they have active axSpA.
- Choice of drug:
    - Extra-articular manifestations and patient choice should be considered when selecting an anti-TNF agent. In the absence of head-to-head studies, systematic reviews have shown no statistical difference in efficacy between infliximab, golimumab, etanercept and adalimumab in the treatment of AS (certolizumab data were not included in these comparative reviews, but its efficacy has been established in clinical trials).

- There are insufficient data to comment on relative efficacy in nr-axSpA. However, not all biologics are licensed for or effective in the treatment of extra-articular disease, so drug choice should take into account co-morbidities and the preferred route and frequency of administration.
- Assessing response:
  - Initial efficacy response should be assessed following 3-6 months of therapy and responders should then be reassessed every 6 months.
- Withdrawal of therapy:
  - In the absence of an initial clinical response by 6 months, or failure to maintain response at two consecutive assessments, withdrawal of that anti-TNF agent should be considered.
  - There is no evidence to support the withdrawal of anti-TNF therapy in treatment responders.
- Switching:
  - In the event of anti-TNF failure due to inefficacy or adverse events, an alternative anti-TNF agent should be offered if clinically appropriate.
- Safety:
  - The safety of anti-TNF therapies in axSpA is comparable to other inflammatory joint diseases such as RA. There is little evidence to suggest that safety issues differ hugely with different disease groups, and the 2010 British Society for Rheumatology (BSR) guidelines on the safety of anti-TNF therapies in RA are applicable in axSpA.

In 2016, the Assessment of Spondyloarthritis International Society (ASAS) and European League Against Rheumatism (EULAR) updated and integrated the recommendations for ankylosing spondylitis (AS) and the recommendations for the use of tumor necrosis factor inhibitors (TNFi) in axial spondyloarthritis (axSpA) into one guideline applicable to the full spectrum of patients with axSpA. The recommendations describe all aspects of the management of patients with a diagnosis of axSpA. The recommendations related to biologic DMARDs (bDMARDs) are:

- bDMARDs should be considered in patients with persistently high disease activity despite conventional treatments (e.g., non-biologic DMARDs); current practice is to start with TNFi therapy.
- If TNFi therapy fails, switching to another TNFi or IL-17i therapy should be considered.
- If a patient is in sustained remission, tapering of a bDMARD can be considered.

Juvenile Idiopathic Arthritis

The 2019 American College of Rheumatology (ACR) and Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis include:

- General medication recommendations for children and adolescents with JIA and polyarthritis:
  - Biologic DMARDS:
    - In children and adolescents with JIA and polyarthritis initiating treatment with a biologic (etanercept, adalimumab, golimumab, abatacept, or tocilizumab), combination therapy with a DMARD is conditionally recommended over biologic monotherapy.
- General guidelines for the initial and subsequent treatment of children and adolescents with JIA and polyarthritis:
  - Initial therapy (all patients):
    - Initial therapy with a DMARD is strongly recommended over NSAID monotherapy.
    - Using methotrexate monotherapy as initial therapy is conditionally recommended over triple DMARD therapy.
  - Initial therapy (patients without risk factors):
    - Initial therapy with a DMARD is conditionally recommended over a biologic.
  - Initial therapy (patients with risk factors):
    - Initial therapy with a DMARD is conditionally recommended over a biologic, recognizing that there are situations where initial therapy that includes a biologic may be preferred. Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
  - Subsequent therapy: Low disease activity (cJADAS-10 ≤ 2.5 and ≥ 1 active joint). For children receiving a DMARD and/or biologic:
    - Escalating therapy is conditionally recommended over no escalation of therapy. Escalation of therapy may include: Intraarticular glucocorticoid injection(s), optimization of DMARD dose, trial of methotrexate if not done, and adding or changing biologic.
  - Subsequent therapy: Moderate/high disease activity (cJADAS-10 > 2.5):

- If patient is receiving DMARD monotherapy: Adding a biologic to original DMARD is conditionally recommended over changing to a second DMARD. Adding a biologic is conditionally recommended over changing to triple DMARD therapy.
- If patient is receiving first TNFi (±DMARD): Switching to a non-TNFi biologic (tocilizumab or abatacept) is conditionally recommended over switching to a second TNFi. A second TNFi may be appropriate for patients with good initial response to their first TNFi (i.e., secondary failure).
- If patient is receiving second biologic: Using TNFi, abatacept, or tocilizumab (depending on prior biologics received) is conditionally recommended over rituximab.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Simponi Aria for intravenous infusion, is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate (MTX), active PsA in patients 2 years of age or older, active AS and active pJIA in patients 2 years of age and older.[1]

Simponi for subcutaneous injection, is indicated in adult patients for the following: treatment of moderately to severely active RA in combination with MTX; treatment of active psoriatic arthritis (PsA) alone, or in combination with MTX; treatment of active ankylosing spondylitis (AS); and the treatment of moderately to severely active ulcerative colitis (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate prior treatment (oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine) for: inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.[7]

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Policy History/Revision Information

Date	Summary of Changes
05/01/2024	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy **Supporting Information** • Archived previous policy version CS2024D0051U

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.